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DOCKET NO. 17629(AP)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bakhit et al.
Serial No.: 10/521,367
Filed: January 12, 2005
Customer No.: 51957
Conf. No.: 2266
Group Art Unit: 1711

For: COMPOSITIONS AND METHODS COMPRISING
PROSTAGLANDIN RELATED COMPOUNDS AND TREFOIL
FACTOR PEPTIDES FOR THE TREATMENT OF GLAUCOMA
WITH REDUCED HYPEREMIA
Examiner: Not Yet Assigned

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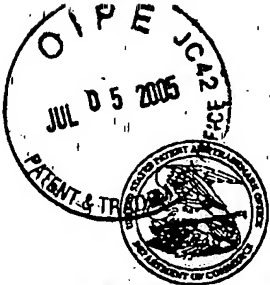
Respectfully submitted,

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Allergan Inc
2525 Dupont Drive
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CONFIRMATION NO. 2266

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Power of Attorney: None

Domestic Priority data as claimed by applicant

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Foreign Applications

Projected Publication Date: 03/02/2006

Non-Publication Request: No

Early Publication Request: No

Title

Compositions and methods comprising prostaglandin related compound and trefoil factor family peptides for the treatment of glaucoma with reduced hyperemia

COMPOUNDS

CPI
Shi



DOCKET 17629 (AP)

COMPOSITIONS AND METHODS COMPRISING PROSTAGLANDIN-RELATED COMPOUNDS AND TREFOIL FACTOR FAMILY PEPTIDES FOR THE TREATMENT OF GLAUCOMA WITH REDUCED HYPEREMIA

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Field of the Invention

The present invention relates to pharmaceutical compositions comprising prostaglandin-related compounds and trefoil factor family peptides.

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Background of the Invention

Description of Related Art

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Active drugs often have undesirable side effects at their therapeutically effective concentrations. This is particularly problematic for topical use in sensitive areas such as the eyes, where irritation is very difficult to avoid even for relatively mild drugs. As a result, formulating topical ophthalmic drugs is a particularly challenging problem. This is unfortunate because topical ophthalmic use of drugs has been found to be very useful in managing many conditions affecting the eye such as dry eye, infection, inflammation, allergy, and glaucoma. Glaucoma is a particularly devastating disease of the eye characterized by increased intraocular pressure, which is often treated by topical ophthalmic application of a drug. Glaucoma occurs in about 2% of all persons over the age of 40 and may be asymptotic for years before progressing to rapid loss of vision. In cases where surgery is not indicated, many drugs have been found to be useful in treating glaucoma by topical application including β -adrenoreceptor antagonists and α_2 -adrenoreceptor agonists. Recently, prostaglandins have been shown to be particularly useful in the topical treatment of glaucoma.

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Whereas prostaglandins appear to be devoid of significant intraocular side effects, ocular surface (conjunctival) hyperemia, foreign-body sensation, and itching (pruritus) have been consistently associated with the topical ocular use of such compounds, in particular $\text{PGF}_2\alpha$ and its prodrugs, e.g., its 1-isopropyl-ester,